The pilot study of efficacy of topical formulation of Henna (Lawsonia inermis)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial

Protocol summary

Study aim
Efficacy of Topical Henna Product in Wound Healing and Pruritus in Patients with Epidermolysis Bullosa

Design
The clinical trial is without control group and without randomization. The outcome of treatment is evaluated by a physician independent of the study. Patients are evaluated every week for one month.

Settings and conduct
Patients entering the study are selected from patients with Epidermolysis bullosa referred to Molecular Dermatology Research Center. The drug is delivered to the patient in 50-gram containers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with Epidermolysis Bullosa; 2. Age over 5 years old; 3. Patient or his/her parent's consent to participate in the study**** Exclusion criteria: 1. Patients younger than 5 years old; 2. Patients or their parents not consenting to participate in the study; 3. Positive history of allergic to Henna; 4. Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)

Intervention groups
Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area

Main outcome variables
Score of itching and wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20150825023753N14

Registration date: 2019-08-31, 1398/06/09
Registration timing: retrospective

Last update: 2019-08-31, 1398/06/09
Update count: 0

Registration date
2019-08-31, 1398/06/09

Registrant information
Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3212 5592

Email address
parvizim@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
2018-09-23, 1397/07/01

Actual recruitment end date
2018-12-21, 1397/09/30

Trial completion date
2019-05-05, 1398/02/15

Scientific title
The pilot study of efficacy of topical formulation of Henna (Lawsonia inermis)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial
Public title
Efficacy of topical formulation of Henna in itching sensation and wound healing in patients with epidermolysis bullosa

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Epidermolysis Bullosa Age over 5 years old
Patient or his/her parent's consent to participate in the study

Exclusion criteria:
Patients younger than 5 years old Patients or their parents not consenting to participate in the study
Positive history of allergic to Henna Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)

Age
From 5 years old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 7
Actual sample size reached: 7

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features
Pilot study, without blinding and randomization

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
7134814336

Approval date
2019-08-14, 1398/05/23

Ethics committee reference number
IR.SUMS.REC.1398.761

Health conditions studied

1
Description of health condition studied
Epidermolysis Bullosa Dystrophica
ICD-10 code
Q81.2

ICD-10 code description
Epidermolysis bullosa dystrophica

Primary outcomes

1
Description
Itching score
Timepoint
Once a week until 1 month
Method of measurement
Visual Analogue Scale (VAS)

2
Description
Percentage of wound healing
Timepoint
Percentage of wound healing
Method of measurement
Clinical global impression of improvement

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Molecular Dermatology Research Center
Full name of responsible person

Approval date
2019-08-14, 1398/05/23

Ethics committee reference number
IR.SUMS.REC.1398.761
Dr. Mohammad Mahdi Parvizi

**Street address**  
Shahid Faghihi Hospital, Zand Avenue

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7134846114

**Phone**  
+98 71 3212 5592

**Email**  
mmparvizi@gmail.com

### Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Younes Ghasemi

**Street address**  
7th floor, Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7134814336

**Phone**  
+98 71 3230 5410

**Email**  
vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Shiraz University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
empty

**Country of origin**

**Type of organization providing the funding**  
Academic

### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi

**Position**  
Assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Traditional Medicine

**Street address**  
Zand Street

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7134844119

**Phone**  
+98 71 3235 1087

**Email**  
mmparvizi@gmail.com

### Person responsible for updating data

**Contact**

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi

**Position**  
Assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Traditional Medicine

**Street address**  
Zand Street

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7134844119

**Phone**  
+98 71 3235 1087

**Email**  
mmparvizi@gmail.com

### Person responsible for general inquiries

**Contact**

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi

**Position**  
Assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Traditional Medicine

**Street address**  
Zand Street

**City**  
Shiraz

**Province**  
Fars

**Postal code**  
7134844119

**Phone**  
+98 71 3235 1087

**Email**  
mmparvizi@gmail.com
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 1087
Email
mmparvizi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic data and the results of the clinical trial

When the data will become available and for how long
6 month later

To whom data/document is available
Researchers

Under which criteria data/document could be used
After publication of the extracted article of the clinical trial

From where data/document is obtainable
Sending Email to the researchers

What processes are involved for a request to access data/document
ارسال درخواست از طریق ایمیل

Comments